I ask my colleagues on the other side of the aisle, Why do you denounce our plans to give working-class Americans some of their own money back through a tax cut? They argue that we cannot afford to give anybody a tax cut. But who is we, Mr. President? Is not we supposed to be the people? And how can Congress not afford to give back to the people something which is actually theirs in the first place?

It is no wonder that some of our colleagues are fighting us every step of the way on our tax-cutting plans. They see the power being stripped away from them, and it scares them.

The $500 per child tax credit is powerful relief for overtaxed American families. Yet, compared against 1 trillion in tax dollars which the Federal Government will collect in 1996, a tax cut that amounts to about $35 billion a year makes a pretty small dent in the national tax bill. But it is a sign that Congress has heard the people, that the tide which has tugged against the taxpayers for so long is finally beginning to shift in another direction, that someone in Washington has finally remembered that it is not the Government's money.

For too many years, Congress has been eating the people's dessert while the people have been eating the gruel. Congress taxes away the workers' college fund or vacation, or their downpayment on a home, and then make the workers come to Washington looking for help. I say it is time we give them a break.

Congress has enjoyed handing out other people's money so much that they have spent all the taxes that I will pay. They have even spent some of the taxes my children will pay, and they have even begun to spend some of the taxes that my grandchildren will pay.

Mr. President, the soul of any democracy is the idea that the power still rests with the people. The only purpose for which power can be rightfully exercised over any member of civilized communities against his will is to prevent harm to others. And that is something that was written by 19th century English economist, John Stewart Mill. His own good, either physical or moral, is not sufficient. All that my freshmen colleagues and I are trying to do is give back to the people the power that rightfully rests with them.

Finally, Mr. President, we will balance the budget. We are going to push ahead with our tax cuts, and at every opportunity, through our legislation or statements on the floor, we will be here to remind our fellow Senators again and again that it is not the Government's money, that it belongs to those who earn it.

Thank you very much.

I yield the floor.

The PRESIDING OFFICER. The Senator from Arkansas.

Mr. PRYOR. Mr. President, I thank the Chair for recognizing me.

Mr. President, I do not know if this is necessary. But I ask unanimous consent that the time I use be taken out of the time as previously under the order allocated to the minority leader, Senator DASCHLE.

The PRESIDING OFFICER. Without objection, it is so ordered.

GATT AND PRESCRIPTION DRUGS

Mr. PRYOR. Mr. President, the Senate is in the midst of a crucial debate over Medicare and Medicaid. In the midst of this controversy, the fate of a single bill or amendment might be inconsequential. But today I rise to discuss a bill which speaks clearly and directly to a very simple question at the heart of all of this debate, and that question is this: Can the Senate do what is best for the American people?

My colleagues, Senator CHAFEE of Rhode Island and Senator BROWN of Colorado, and I have offered just such a proposal. Compared with the matter that we began debate on Wednesday in the reconciliation bill, our proposal is simple, and it is easy to miss. But it is important. It is crucial. It admits a congressional mistake, and it fixes a congressional mistake. It closes a glaring legislative loophole and saves billions of dollars in the process.

But, most important, it sends a very simple message to the American people: Congress makes mistakes, but Congress can fix those mistakes when the interests of the American people are at stake.

Mr. President, we offered this bill because the interests of the American people—both as taxpayers and as consumers—are clearly at stake here. And deep down my colleagues know it, too.

Let me briefly describe our proposal. It enjoys broad bipartisan support in the Senate and in the House and has been endorsed by every single Federal agency involved with trade, patents, or drugs: the U.S. Trade Representative, the Patent and Trademark Office, and the Food and Drug Administration.

Mr. President, here is what it does: When Congress passed the GATT Treaty last year, we enacted two transition provisions. First, we granted a generous extension to all current patents. Second, as a condition of that extension, we permitted generic competitors onto the market on the old patent expiration date if they had already made a substantial investment and were willing to pay a royalty. That was our agreement. That was our discussion as it related to GATT. These changes were universally understood by all of the negotiators from every country, from every industry, from every economic aspect of our economic life in America.

Let me be very clear on this point. U.S. Trade Representative Mickey Kantor states categorically in a letter dated September 18 to me that the law was meant to apply universally, that there would be no exceptions. The GATT negotiators themselves—the experts who physically sat down at the table and negotiated the GATT Treaty on behalf of the United States—have personally confirmed that the transition provisions were meant to apply to every single person, product, company, and industry in the country.

There was a loophole. And guess who came out smelling like a rose? A few pharmaceutical drug companies, who now—if we do not do something about it—are going to have a free ride for the next 3 years when generic competition is poised and ready to compete with them in the marketplace.

This spring the Congress discovered this loophole. We failed to modify this loophole in the Finance Committee because of a technical problem. When we passed the GATT Treaty, we inadvertently gave the prescription drug industry a giant unintended windfall. Of all the companies, of all the products in America—from automobiles to zippers, computers and TV parts, everything—only prescription drug companies, only drug companies, received a competition-free patent extension, a free ride, a windfall.

In fact, when one of the officials of Glaxo Co., that manufactures Zantac, heard about this loophole being discovered, his first word was—and I quote—''eureka.'' They got the extension, and they were mistakenly shielded from the competition intended by GATT. Without that competition, today a handful of drug companies are now, beginning today, receiving a whopping multibillion-dollar windfall paid for by consumers and paid for by taxpayers.

This was a simple mistake of oversight, Mr. President. I wish to emphasize that. We make mistakes around here every day. Sometimes we correct them and sometimes we do not. But this is an opportunity to correct that mistake. Every authority that I have spoken to, every Member of this body, every Senate committee, and every Government agency admits this was an error, and now we have a chance to change it. Even the companies that gained this unjustified multibillion-dollar windfall admit it was a mistake.

This is why my colleagues, Senators CHAFEE and BROWN and myself, will be offering this amendment. This amendment does one thing and one thing only. It applies GATT to those few drug companies the same way it applies to every other company and every other product in this country. Unless we correct this loophole today, enormous profits, unjustified and unexpected, will go to those few companies. We have already taken the first steps to a solution, but 3 weeks ago we were blocked by a procedural technicality in the Finance Committee. And make no mistake. The only way to rectify this problem is here and it is now. The Senate is the court of appeals for this issue to be decided.

If there is any doubt whether Congress should fix its own mistakes, I have some news for my distinguished colleagues. The Patent Office and the FDA have tried to correct this problem on their own. They failed because of

technicalities. The problem is, their hands are tied by the letter of the law in the GATT treaty.

On last Thursday, despite their best efforts, a Federal court held that three drug makers that had filed suits in the court had actually won, which meant that they ruled against this loophole being corrected. The Federal court said that their hands were tied.

Even worse, the court ruling now means that potentially hundreds of products could be affected. This could mean as much as $6 billion—I repeat, $6 billion—in unnecessary health care costs for every purchaser of prescription drugs—the elderly, hospitals, clinics, HMO's, drugstores, insurance companies and, not the least, the governments, State and Federal governments.

According to securities analyists, the ruling could ''affect sales of billions of dollars of brand name drugs that would otherwise be open to competition from less expensive generic versions.''

For the average person, this means money out of our pockets for no good reason. If they are one of the millions of people who take the world's best selling drug, Zantac, our legislation would cut the cost of Zantac by one-half. Think of it, cutting the cost of one medication by one-half that is the best selling drug in America.

Our legislation would cut the cost of Capoten for hypertension by two-thirds. By over 65 percent we would cut the cost of this drug simply because there would be competition in the marketplace. That competition in the marketplace is going to be delayed unless the court of appeals, in this case the U.S. Senate, the last court of appeals, handles this matter and corrects this very tragic mistake.

Let me tell you three other reasons why we should be supporting this amendment at the proper time. Our proposal will save the Government hundreds of millions of dollars for the poor, the veterans, active military personnel, pregnant women, Native Americans, and every American served by Medicaid, the Department of Veterans Affairs, the Department of Defense, as well as the Public Health Service and the Indian Health Service clinics. All of those would be included and all of those would benefit with the adoption of our proposal.

Second, everyone wants to do what is best for older Americans, the sick and the poor and the consumers. How often do we hear that? Here we have an opportunity to do it. It is clear. It is evident that we can help these groups by supporting this idea. Our proposal is supported by senior citizens, consumers, medical practitioners. It is endorsed by the National Council on the Aging, National Consumers League, the Gray Panthers, the National Women's Health Network, the United Homeowners Association, the National Council of Senior Citizens, and the National Black Women's Health Project.

Finally, this issue has been the focus of intense media scrutiny for the last several weeks. People are beginning to see how a big ripoff is about to happen unless we correct it. Articles and stories inspired by disbelief have appeared in the New York Times, NBC News, Associated Press, Los Angeles Times, Business Week, Reuters, Journal of Commerce, Roll Call, and the Orlando Sentinel, and the list goes on and on.

Why is there so much attention on this issue? Well, the bottom line is there is a lot of money at stake. There are multibillion-dollar health care cuts being debated in Congress today, and here we are about to give an enormous windfall to one of the most profitable segments of our economic activity, the pharmaceutical companies.

Why does anyone care about this particular legislation? I think the reason people care is because they know this bill is the right thing to do. They are sick and tired of the excuses that are given when we fail to do the right thing. Please let me repeat, this is not a partisan issue. It never has been. It is about fixing a mistake. It is about saving taxpayers' money. It is about precluding an enormous windfall in unjustified profit to several drug companies that have gotten, in my opinion, extremely greedy.

This morning, Mr. President, I was just handed a page from the Roll Call newspaper, dated Monday, October 23, 1995, page 8. Here is an advertisement placed by the American pharmaceutical research companies—by the way, that is the old PMA—Pharmaceutical Manufacturers Association. They changed their name a few months ago, Mr. President, so they could add a little cloak of dignity emphasizing research. They take what we are trying to do apart and they try, as they say, separating fact from fiction in this particular ad. But the bottom line is what they have said is extremely misleading. It is motivated by economic gain. In addition to that, it is simply wrong. The motivation for this particular advertisement, in my opinion, is the continuation of economic greed by some of the pharmaceutical manufacturers.

Just in the Wall Street Journal, I believe, on Friday, the drug companies talked about, well, they cannot sell drugs in America as cheaply as they can sell these same drugs in Europe or in the other industrialized nations. Look at this headline: ''Strong Global Sales Lift Drug Company Profits.'' So they are selling overseas these same drugs they sell to us for 40 and 50 and 60 percent more in this country, they sell these drugs overseas at so much less and they are making such an enormous profit that they see their stock is going up in these companies, and once again the drug companies find a way to take advantage of the American consumer and certainly the American taxpayer. If we do not correct this issue now, we are going to be actually a part, in my opinion, of a terrible mistake that we had a chance to correct.

Here is the alternative, Mr. President. We can stand here and do nothing, we can let these drug companies make off like bandits with these unjustified profits, or we can vote for the amendment offered by myself and, hopefully, some of my other colleagues. We can rob older Americans, HMO's and every single taxpayer in this country if we do nothing. We can enrich two or three drug companies, we can keep competition out of the market, or we can make certain that they do not receive money they do not deserve.

We can let a loophole rob American consumers of as much as $6 billion. We can let the intense lobbying efforts by one or two drug companies sway us. We can ensure special treatment to a few companies while the rest of the country plays fair, following the rules and obeying the law.

Once again, Mr. President, a few pharmaceutical drug companies are the only companies that are excluded under this provision. They are the only ones given this mistake. They are the ones taking advantage, I should say, of this mistake in the GATT treaty. Now is our opportunity to change it. And in my opinion, Mr. President, this is the mother of all special interest issues.

Let me read from the New York Times when they observed a few days ago:

> Some of the Nation's largest drug companies will have spent and lobbied heavily against one bill that hardly amounts to budget dust. While its impact on the Federal budget may be minuscule, the measure means a fortune to these drug companies.

Mr. President, I urge my colleagues to join us in supporting this proposal. If we fail, it will allow the legal combination of a legal loophole, a procedural technicality, intense lobbying, big bucks, and our own failure of will, robbing the American consumers of billions of their taxes and their income. Every American citizen will be forced to continue subsidizing an outrageous, unintended windfall to a handful of drug companies simply because we do not have the courage or the foresight or the will to admit and to fix our own mistakes.

Mr. President, I ask unanimous consent that documentation of savings from this proposal, letters of support, and recent media articles be printed at this point in the RECORD.

There being no objection, the material was ordered to be printed in the RECORD, as follows:

[From the New York Times, Oct. 20, 1995]

THREE DRUG MAKERS WIN SUIT TO EXTEND PROTECTION OF PATENTS

ALEXANDRIA, VA.—Merck & Company, the Schering Plough Corporation, and Roche Holding A.G., have won a lawsuit against the United States Patent Office and the Food and Drug Administration, in which they had sought an extension on some of their patents.

The ruling, reached Monday by the Federal District Court here, is a victory for brand-name drug makers who fought a decision by the F.D.A. and the Patent Office to limit patent protection.

Securities analysis said the ruling could affect sales of billions of dollars of brand-

name drugs that would otherwise be open sooner to sharp competition from less expensive generic versions.

Neil B. Sweig, an analyst with Brown Brothers Harriman & Company, said that based on current sales in the United States, the extension could result in $3 billion in sales of Zantac, the ulcer treatment made by the Glaxo Wellcome Company; $1.45 billion in sales of Mevacor, a cholesterol-lowering drug made by Merck, and $280 million in sales of Capoten, a hypertension treatment produced by the Bristol-Myers Squibb Company.

Mr. Sweig added that the court ruling had been anticipated by investors and was already reflected in drug companies' stock prices.

Under a Federal rule that took effect on June 8, drug makers could either have patent protection under the new world trade organization or the previous system.

The new patent protection for brand-name drugs would last as long as 20 years from the date of the patent filing. Under the old system, drug patents were protected in the United States for 17 years after they were granted, plus some of the time drugs were waiting, regulatory review by the F.D.A. In some cases, protection would last longer under the old system.

''The courts ruled that they were wrong, and you can be protected under both systems,'' said Steve Bercham of the Pharmaceutical Manufacturers Association.

Mr. Bercham said, however, that the court had decided that a patent could never result in exclusive marketing rights for more than 14 years.

As a result of the decision, Merck's patent on its cholesterol-lowering drug Mevacor was extended to June 15, 2001, from Nov. 4, 1999.

Gary Latchow, a Merck spokesman, said the patent for the company's ulcer medication Pepcid had also been extended.

U.S. TRADE REPRESENTATIVE,
Washington, DC, September 18, 1995.

Hon. DAVID PRYOR,
U.S. Senate, Russell Senate Office Building, Washington, DC.

DEAR SENATOR PRYOR: Thank you for your recent letter updating me on the ongoing concerns of the Congress, health care purchasers and consumers over the exclusion of the prescription drug industry from the scope of the Uruguay Round Agreements Act (URAA) transitional ''grandfather'' provision.

As you note in your letter, I wrote to Food and Drug Administration (FDA) Commissioner Kessler earlier this year to inform him that the URAA ''grandfater'' provision language was intended by its drafters to be generally applicable and to permit generic pharmaceutical producers to market their products where they had made substantial investments in anticipation of the expiration of the unextended patent terms. While the FDA found that the URAA did not permit it to allow the generic pharmaceutical producers on the market until the expiration of the extended patent term, it stated that ''the language of the URAA does not reflect the legislative intent'' which Congress desired.

In light of these events, I applaud your effort to seek to correct this situation through your introduction of the Consumer Access to Prescription Drugs Act. The draft legislation generally reflects the intent of the drafters of the URAA.

With regard to the issue of whether this correction would either weaken patent protection under the URAA or diminish our ability to campaign for stronger patent protection abroad, I believe that any concerns in this area are overstated. As you know, we intended to apply this ''grandfather'' provision to the pharmaceutical area, and so legislation of this type should result in a level of protection that is consistent with our original intent. Additionally, this level of protection is consistent with the obligations under the intellectual property agreement negotiated as part of the Uruguay Round, called the ''TRIPs Agreement.'' Just as we are permitted to make limited exceptions to the grant of additional rights as the result of the TRIPs Agreement, so are our trading partners. As we have already made certain exceptions to the rights granted during the extension period for all types of patents other than pharmaceutical patents, the application of these exceptions to pharmaceutical patents should not weaken our ability to insist on strong patent protection in our trading partners. You can be sure that if a trading partner attempts to expand these exceptions beyond those permitted by the Agreement, we will vigorously oppose them.

Consequently, I do not think that your efforts will have a negative effect on our ability to ensure that the TRIPs Agreement is fully implemented by our trading partners. I look forward to working with you on this issue.

Sincerely,

MICHAEL KANTOR.

U.S. TRADE REPRESENTATIVE,
Washington, DC, September 25, 1995.

Hon. JOHN H. CHAFEE,
U.S. Senate,
Washington, DC.

DEAR SENATOR CHAFEE: Thank you for your letter concerning the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPs) and the intended effect of certain provisions of the Uruguay Round Agreements Act (URAA). You raise several significant issues related to the nature of the United States' obligations under the TRIPs Agreement and the way in which the United States implemented those obligations in the URAA. In answering your questions, I would like first to indicate the nature of certain of the obligations under the TRIPs Agreement, and then to discuss the provisions in the URAA that are intended to implement those obligations.

U.S. OBLIGATIONS UNDER ARTICLE 70 OF THE TRIPS AGREEMENT

Article 70 of the TRIPs Agreement generally requires World Trade Organization (WTO) Members to apply the high levels of protection required by the TRIPs Agreement to all existing intellectual property. In other words, if a WTO Member provides an additional right or benefit to the owners of a particular type of intellectual property as a result of its implementation of the TRIPs Agreement, it must provide that additional right or benefit to intellectual property created in the future *and* to intellectual property already created but still subject to protection. Accordingly, in the URAA the United States modified the term of patents from seventeen years from grant to twenty years from application for all future patents, and also applied the new term to existing patents, thereby giving some owners of U.S. patents a longer term of protection.

The primary provisions of Article 70 on treatment of existing subject matter and ''newly infringing acts'' are Articles 70:2, 70:3 and 70:4. Article 70:2 contains the general requirement that TRIPs-consistent levels of protection must be applied to existing intellectual property. Article 70:2 also states that in the case of copyrightable subject matter (e.g., books, movies, sound recordings, computer software), copyright obligations, including the grant of retroactive protection must be implemented solely through the application of Article 18 of the Berne Convention for the Protection of Literary and Artistic Works. This provision makes clear that where copyrightable subject matter must be pulled out of the public domain and granted protection to comply with TRIPs, the terms of Article 18 of the Berne Convention shall control.

Article 70:3 of the TRIPs Agreement provides that no WTO Member is obligated to restore protection to subject matter which has fallen into the public domain. For example, an expired patent need not be granted a new term of protection, even if the patent would still be in effect had it been granted a TRIPs-consistent term of protection. As noted above, Article 70:2 expressly carves-out copyright protection from Article 70:3.

Article 70:4 provides that to the extent that certain activities become infringing because of the higher levels of protection required by TRIPs, WTO Members may allow a person to engage in such infringing acts as long as they pay equitable remuneration to the right holder. This provision was intended to permit WTO Members to treat equitably those persons who in good faith used or made a significant investment in connection with the use of the intellectual property right in a way that would be prohibited after a TRIPs-consistent level of protection applied. For example, if TRIPs requires an extension of the patent term in a WTO Member, that Member may allow a person who built a factory for the purpose of manufacturing a patented product when the patent was previously expected to expire to make the produce during the extension period, as long as that person pays equitable remuneration to the right holder during the extension period.

Consequently, while Article 70:4 could apply to treatment of inventory created before the application of the Agreement, it was not intended to be limited to that situation. The primary intent of this provision was to treat equitably those persons who had made a substantial investment in reliance on the pre-TRIPs level of protection. It was not intended to allow nations with weak patent laws to protect domestic industries while those nations came into conformity with the new TRIPs standards. Investment must be substantial and it must be made by a certain date.

U.S. IMPLEMENTATION OF ARTICLE 70 OF THE TRIPS AGREEMENT

The United States implemented its obligations under the TRIPs Agreement in Sections 501–532 of the URAA. Section 532(a) of the URAA amended Section 154 of the Patent Act to change patent terms from a seventeen years from grant system to a twenty years from application system. As noted above, in accordance with our TRIPs Article 70:2 obligations, Section 154(c)(1) of the Patent Act was amended to grant owners of patents still in force the benefit of this new system to the extent it increased their term.

To treat equitably those persons who had made a substantial investment in reliance on the old patent term, Section 154(c) (1) and (2) of the Patent Act was amended to provide that such persons would be able to make use of the patent during the extension term as long as they paid equitable remuneration to the patent owner. This provision was written neutrally because it was intended to apply to all types of patentable subject matter, including pharmaceutical products. Conforming amendments should have been made to the Federal Food Drug and Cosmetic Act and Section 271 of the Patent Act, but were inadvertently overlooked.

Our creation of the ''transition period'' in Article 154(c) of the Patent Act is consistent with our obligations under the TRIPs Agreement. The extension of this transition period

to pharmaceutical products would also be consistent with these obligations and the intent of the U.S. negotiators involved in drafting the TRIPs Agreement.

Finally, the extension of the Section 154(c) to pharmaceutical products would not undermine ongoing U.S. efforts to seek high levels of intellectual property protection around the world. We are acting wholly within our rights in establishing the transition period, as other countries would be if they did the same. Furthermore, we have already established under our law the transition period with respect to all types of patents other than pharmaceutical patents; extending it to pharmaceutical patents would in no way increase the ability of our trading partners to justify their failure to provide TRIPs-consistent patent protection. You can be sure that if one of our trading partners attempts to overstep the equitable treatment permitted under TRIPs Article 70:4, or otherwise fails to live up to the TRIPs Agreement, we will work vigorously to bring them into compliance with their international obligations.

I look forward to working with you further on this manner. Please let me know if I can provide you with any more information.

Sincerely,

MICHAEL KANTOR.

[From Prime Institute, College of Pharmacy, University of Minnesota, Health Sciences Unit F–7–159, Minneapolis, MN, March 1995]

ECONOMIC IMPACT OF GATT PATENT EXTENSION ON CURRENTLY MARKETED DRUGS

EXECUTIVE SUMMARY

At least 109 currently patented and marketed drugs will receive a windfall patent extension if GATT rules are retrospectively applied to previously filed or issued patents.

The average patent extension for the currently marketed drugs would be more than 12 months with some drugs receiving more than 28 months of added exclusivity.

The windfall extension of patent exclusivity for currently marketed drugs will mean that the introduction of lower cost generics will be delayed. Therefore, the American consumer will have to pay more for prescription medications.

FDA approved versions of generic drug products typically enter the market at a price more than 25% less than the patented brand. Within one year the price of competing generics will be 45% below the brand; at two years the price will be 60% less and at three years it will average 75% less than the brand name drug (Kidder, Peabody: Generic Drug Industry Overview, October 5, 1994).

FDA approved versions of generic drug products typically capture 45% of the units sold within one year of market introduction. After two years their market penetration averages more than 50% of all units sold and by the third year the penetration approaches 60% (Kidder, Peabody: Generic Drug Industry Overview, October 5, 1994).

The economic impact of extending the GATT rules to currently marketed drugs can be estimated by applying the recent pricing and market penetration performance of generics to the actual and projected sales volume of currently marketed drugs for the additional length of time that American consumers will have to wait for access to lower cost generics.

The projected cost to American consumers from the windfall extension of patent exclusivity for the 109 currently marketed drugs affected by this change will exceed $6 billion (1996 net present value) over the next two decades.

Twenty of the most common prescription drugs will account for an increased cost to American consumers of over $4.5 billion (1996 net present value) in the next two decades.

There are at least 10 drugs whose patents will expire in 1995. The lack of generic competitors for just three of these drugs will cost American consumers $1.2 billion (1996 net present value) in 1996 and 1997.

The lower price and high market penetration of generics, when available, results in substantial savings to American consumers. These savings are also of benefit to Medicaid, federal and state government, private insurers, managed care, employers, unions, ERISA plans, and others who pay for prescriptions. The cost of this windfall extension of exclusivity to Medicaid alone will be about $1 billion (1996 net present value) and the total cost to federal and state government will exceed $1.25 billion (1996 net present value).

The projected cost to American consumers from the extension of GATT rules to currently marketed drugs has been estimated in a study conducted by the PRIME Institute at the University of Minnesota. The PRIME Institute specializes in research involving pharmaceutical benefit management, economics, and public policy issues.

[From the Associated Press, Oct. 19, 1995]

DRUGS GET EXTRA PATENT TIME

WASHINGTON.—A federal court has decided nearly 100 brand-name drugs may get an extra few years' monopoly in the market, the pharmaceutical industry announced Thursday.

At issue is whether the drugs could get two patent extensions—one from a 1984 law and another under a global trade agreement.

The General Agreement on Tariffs and Trade, which went into effect in June, extends patent protection to 20 years from the date drug makers file for a patent. Until now, those patents have had a 17-year life from the time they were granted. Current patent-holders will get whichever expiration date is later.

A 1984 law already has offered brand-name drugs up to an extra five years' patent life to help offset the time it takes those medicines to get Food and Drug Administration approval for sale.

Makers of brand-name drugs said they were entitled to both extensions, which could have given some drugs patent protection for a total of 25 years.

But the Patent and Trademark Office decided in June that drugs that got the 1984 extension couldn't get one from GATT too. The ruling affected 94 brand-name drugs and meant the longest a medicine could monopolize the market was about 22 years.

The drug industry went to court. Thursday, the Pharmaceutical Research and Manufacturers Association announced that a U.S. District Court in Alexandria, Va., had ruled that both extensions were the law.

[From the Roll Call, Oct. 5, 1995]

SIMPSON ABSTAINS BECAUSE OF STOCK

(By Amy Keller)

In an unusual acknowledgment of the potential conflict created by Members' financial holdings. Sen. Alan Simpson (R-Wyo) abstained from a Finance Committee vote Friday on an amendment that could affect two major pharmaceutical companies in which he owns thousands of dollars worth of stock. Simpson, who chairs the Finance subcommittee on Social Security and family policy, abstained from voting on an amendment offered by Sens. David Pryor (D-Ark) and John Chafee (R-RI), which according to Pryor would ''close a multibillion-dollar loophole in the General Agreement on Tariffs and Trade for the name-brand pharmaceutical industry.''

According to his 1994 financial disclosure forms, Simpson owns between $1,000 and $15,000 worth of stock in both Glaxo-Wellcome PLC and Bristol-Myers Squibb Co.—two pharmaceutical companies that stand to lose millions of dollars if the Pryor-Chafee amendment is enacted.

Simpson said yesterday that he ''just didn't feel comfortable'' voting on the amendment.

''I abstained . . . simply because I own about . . . four or five thousand bucks of Glaxo stock. . . . It is a serious amendment and I just chose to abstain,'' Simpson said.

The amendment seeks to put an end to exemptions granted to name-brand pharmaceutical companies allowing them patent extensions on drugs.

As Pryor explains it, through GATT, the US ''agreed to extend patents [on all sorts of products] we grant from 17 years to 20 years to conform with the rest of the world,'' but the treaty also included language to allow ''generic manufacturers to come on the market after the 17-year term ended if they agreed to pay a sort of franchise fee to the brand-name company.''

After heavily lobbying Congress to keep the 20-year patent extensions under the treaty, the pharmaceutical industry was granted ''special protection'' for some 100 specific drugs.

The United States Patent and Trademark Office later revoked the protection of 94 of those drugs, and the Pryor-Chafee amendment seeks to revoke the 20-year patents of the handful of drugs that still carry such protection.

Citing a study by the University of Minnesota, Pryor contends that Glaxo, which makes the ulcer drug Zantac prescribed to some 33 million Americans and is the world's largest pharmaceutical company, and Bristol-Myers Squibb, maker of the blood pressure medication Capoten (prescribed to some 15 million), could net a ''windfall'' of $1 billion and $100 million, respectively, if generic companies are prevented from manufacturing the drugs for an additional three years.

Despite a 9–7 vote in favor of the amendment, the measure failed when Finance Chairman Bill Roth (R-Del) ruled that the amendment to the budget reconciliation bill was out of order. Roth said the amendment was nongermane, thus requiring a two-thirds majority vote for passage instead of a simple majority.

Three other members of the 19-member Finance Committee—Sens. Bob Dole (R-Kan) and Larry Pressler (R-SD) and then-Sen. Bob Packwood (R-Ore),—also abstained from voting on the amendment.

According to Pryor press secretary Justin Johnson, Pressler and Dole had prepared ''no'' votes by proxy and only abstained from voting on the amendment when it became apparent the amendment would fail with or without their votes.

And while Dole has no direct holdings in pharmaceutical stock, his wife Elizabeth owns between $1,000 and $15,000 in Bristol-Myers Squibb stock, and she holds between $1,000 and $15,000 in Kimberly-Clark Company stock, another major pharmaceutical corporation, according to 1994 financial disclosure records.

Pryor and Chafee have not given up the fight on their amendment, however, and plan to raise the issue on the Senate floor in the near future. According to Johnson, there will be a modification to the amendment and it will be re-offered.

And should the Pryor-Chafee amendment make it to the Senate floor, at least five of Simpson's colleagues will face the same choice the Senator did last week, on whether to vote on a measure that could constitute a conflict of interest in light of their private investments.

Among those also owning stock in the affected pharmaceutical companies according to their 1994 financial disclosure records are: Sens. Paul Coverdell (R-Ga), who holds between $1,000 and $15,000 in Glaxo; Judd Gregg (R-NH), between $100,000 and $500,000 in Bristol-Myers Squibb; James Inhofe (R-Okla), between $1,000 and $15,000 in Bristol-Myers Squibb; Lauch Faircloth (R-NC), between $1,000 and $15,000 in Glaxo; and Claiborne Pell (D-RI), between $1,000 and $15,000 in Bristol-Myers Squibb.

Simpson said he doesn't know if he will again abstain from voting on the Pryor-Chafee amendment if it reaches the Senate floor.

''I'll go sort it out again and see where we are, but at least everybody will know that I have that type of holding in Glaxo, which is listed in my [financial disclosure] reports anyway,'' Simpson said.

According to Rule 37 of the Senate Code of Official Conduct, no Senator shall ''knowingly use his official position to introduce or aid the progress or passage of legislation, a principal purpose of which is to further only his pecuniary interest. . . .''

Still, it is exceedingly rare for lawmakers to abstain themselves from a vote, an ethics expert confirmed.

According to former House Counsel Stan Brand, ''[Conflict of interest] is something that has been broadly construed in the annals of ethical rule of the House and Senate, and it's only in the most acute cases of a conflict that [someone] is actually barred from voting.''

In the first half of 1995, Glaxo-Wellcome's PAC gave $94,300 in political contributions to Republicans and $28,500 to Democrats, while Bristol-Myers Squibb's PAC gave $22,800 to Republicans and $7,300 to Democrats, according to Federal Election Commission records.

Five members of the Senate Finance Committee—Sens. Max Baucus (D-Mont), Alfonse D'Amato (R-NY), Charles Grassley (R-Iowa), Frank Murkowski (R-Alaska), Pressler, and Simpson—received political contributions from Glaxo.

Baucus and D'Amato each also received contributions from Bristol-Myers Squibb.

[From the Reuter Business Report, Sept. 29, 1995]

DRUG COMPANY PRESERVES TAX BREAK IN SENATE COMMITTEE

(By David Lawsky)

A major drug company Friday won a fight in a Senate committee, holding on to a loophole that opponents said will cost consumers $3.6 billion.

The Senate Finance Committee, which is considering an omnibus budget bill, turned down an attempt to remove the special treatment for Glaxo Holding PLC and other brand name drug companies.

Those against the break promised to bring the fight up again on the floor of the Senate.

Sen. John Chafee, R-R.I., proposed ending the break for Glaxo because he said it was ''unanticipated and totally inadvertent.'' In fact, Chafee said, when the lawyer for Glaxo discovered the loophole, he said he had a '''Eureka!' moment.''

''I might say he's entitled to shout 'Eureka!' when you've got $3.6 billion'' at stake.

A study cited by Chafee showed that without cheaper competition by generic drug companies 13 drug companies stood to reap $4.3 billion, with Glaxo getting most of it.

Chairman William Roth, R-Del., ruled Chafee's motion out of order. To the consternation of Chafee and his allies, Roth said he was going to require a two-thirds vote to overturn him, citing a rule.

''Mr. Chairman I've never known us to require a two-thirds vote'' in such a situation, said Sen. Daniel Patrick Moynihan, D-N.Y., who was chairman when Democrats held a majority.

But Roth held firm and although the committee voted 9–7 to remove the break, Chafee lost.

The issue arose out of the General Agreement on Tariffs and Trade, which has a section that in many cases stretched patents from 17 to 20 years.

But that section would put generic companies at a disadvantage if they had made expensive preparations to go into business against a patent-holder, anticipating the end of 17-year patents.

So a special section was adopted that permitted companies that had sunk money into competition to go ahead and market their competing product, so long as they paid royalties to the brand name company which won the extra patent time.

U.S. Trade Representative Mickey Kantor said this week in a letter to Chafee the section was supposed to apply to all products but that ''pharmaceutical products . . . were inadvertently overlooked,'' because they needed a special change in the law governing the Food and Drug Administration.

The measure was opposed by Sen. Orrin Hatch, R-Utah, who called it ''complex,'' and by Sen. Carol Moseley-Braun, D-Ill., who said through a spokeswoman she was a friend of the president of Glaxo and had traveled on the company plane to speak at its headquarters.

[From the Orlando Sentinel, Sept. 30, 1995]

GENERIC-DRUG TALKS STALL IN COMMITTEE

(By Maya Bell)

A bill that would allow generic-drug companies to begin competing with brand-name rivals suffered a setback in Congress on Friday.

The Senate Finance Committee voted 9–7 to consider correcting a congressional oversight that protected the makers of 13 brand-name drugs from generic competition for up to three years. Among the drugs are two best-sellers, Zantac for ulcers and Capoten for high blood pressure.

But committee Chairman William Roth, R-Del., ruled that two-thirds of the committee had to agree to debate the bill. Lacking that majority, the amendment was tabled.

''It's still a victory. The reason we couldn't get a hearing was procedural,'' said Natalie Shear, a spokeswoman for the Generic Drug Equity Coalition, a consortium of consumer groups and generic-drug companies lobbying Congress to correct its mistake. ''The bottom line was the senators indicated their support.''

Sen. Bob Graham, the only Floridian on the committee, voted to consider the bill.

A spokesman for one of the sponsors, Sen. Richard Pryor, D-Ark., said the measure would be brought up again in another forum.

''It's definitely not dead yet,'' said Justin Johnson, Pryor's press secretary. ''There will be a modification, and it will be reoffered. We'll keep after it.''

The bill is intended to correct what is widely acknowledged to have been a congressional oversight. The mistake was made when Congress adopted the language for the global trade treaty known as GATT. While extending U.S. patent terms from 17 years to 20 years to comply with the General Agreement on Trade and Tariffs, Congress inadvertently exempted 13 brand-name drugs from generic competition for up to three years.

The drug coalition estimates that the oversight will cost consumers, who won't have generic alternatives for some prescriptions as early as anticipated, nearly $2 billion.

Among the biggest beneficiaries are drug giants Glaxo-Wellcome Inc., the makers of Zantac, and Bristol-Myers Squibb Co., which produces Capoten. Last year, Glaxo sold $2.7 billion worth of Zantac and Bristol-Myers $581 million of Capoten in the United States.

Neither company could be reached for comment Friday. Glaxo spokeswoman Nancy Pekarek has said the company opposes the GATT fix because it would send a message to other countries that they, too, can tinker with the treaty to protect a favored industry.

[From the Journal of Commerce, Sept. 28, 1995]

DRUG FIRMS FIGHT TO PRESERVE WINDFALL

(By John Maggs)

WASHINGTON.—A handful of powerful drug companies are waging one of the most furious and extravagant lobbying campaigns seen on Capitol Hill in years, all to preserve an inadvertent change to U.S. law in last fall's trade bill that promises them billions of dollars in unexpected profit.

The drug companies are shelling out millions of dollars to enlist the influence of distinguished former senators such as Warren Rudman of New Hampshire and Dennis DeConcini of Arizona, and former U.S. Trade Representative and Senator William Brock of Tennessee.

The prize for this largess is one of the biggest payoffs for the smallest number of companies ever granted by Congress without a word of debate.

One company alone, Britain's Glaxo Holdings PLC, will rake in $3.6 billion over the next two years as a result of this legal twist of fate, all of it money that it never expected to earn. This windfall will come out of the pockets of ulcer patients, most of them in the United States, who will pay higher prices for Glaxo's revolutionary anti-ulcer drug Zantac.

The explanation begins with last year's bill to implement the Uruguay Round trade agreement, which lowered trade barriers worldwide and increased protection for patented drugs and copyrighted material. As part of that international patent deal, the United States agreed to change the life of new patents from 17 years after they are first granted to the norm for the rest of the world—20 years from the date a patent request is first made.

The trade legislation sent to Congress made the patent term change effective for all patents, so that those coming due less than 20 years after they were originally filed were automatically granted an extension. Mindful that this would have handed drug companies an unwarranted windfall, the trade bill provided that generic drug firms would be allowed to begin manufacturing the patented drugs after the original patent date, provided they pay a licensing fee to the big drug companies.

But unknown to the drafters of this legislation, a 1984 drug law effectively freed Glaxo and other big pharmaceutical companies from this obligation to license their products. In a moment of insight a lawyer for Glaxo discovered this overlooked statute, and set off a bitter fight with generic drug companies to reverse this inadvertent stroke of good luck.

This list of beneficiaries is a long one. Glaxo is by far the biggest—it will receive nearly two years of extra monopoly control over Zantac, earning $6 million a day more than it would have earned if competing with generic drug producers. Also benefitting are Squibb, which will get $311 million of added profits for its ACE hypertension drug; Organon, which gets $108 billion for its Norcoron anestesia; and Searle, which gets $102 million for its Cytolec anti-ulcer drug.

Advocates of the generics have lined up the support of U.S. Trade Representative Mickey

Kantor in arguing that the windfall was an inadvertent one.

As soon as today, Sens. David Pryor, D-Ark., and John Chafee, R-R.I., are expected to offer an amendment to reverse this windfall profit, but they face an uphill battle. Sen. Jesse Helms, R-N.C., is leading the fight for Glaxo, whose U.S. subsidiary is based in North Carolina. Sen. Helms faces re-election in 1996 and some of Zantac's billions of dollars in earnings would be useful in financing his campaign.

Sen. Helms has lined up the support of majority leader Bob Dole, who has in turn made preserving the windfall for the drug companies a partisan issue. Few Republicans other than Sen. Chafee have committed to support the Pryor amendment.

[From the Journal of Commerce, Oct. 2, 1995]

SENATE PANEL: NO VOTE ON DRUG LOOPHOLE

WASHINGTON.—Senate Finance Committee Chairman Bill Roth, R-Del., refused to allow a vote to repeal a controversial loophole in U.S. patent law, despite opposition to his unusual ruling from a bipartisan majority of the committee.

Behind the maneuvering was a huge amount of money for British-owned Glaxo Holding PLC and the tight grip that Senate Majority Leader Bob Dole, R-Kan., holds over the Finance Committee.

The issue apparently resulted from an inadvertent mistake in drafting last fall's trade bill, which gave Glaxo an unexpected windfall of $3.6 billion by extending for two years its exclusive patent rights on the anti-ulcer medicine Zantac.

Generic drug companies are clamoring to put out knock-off versions of Zantac, but cannot because government lawyers drafting the trade bill overlooked a 1984 law that effectively prevented these generics from starting production. Career trade negotiators who worked on the legislation confirmed Friday that it was an oversight.

Sens. John Chafee, R-R.I., and David Pryor, D-Ark., Friday sought to reverse this mistake with an amendment to the huge budget reconciliation bill before the Finance Committee. Although Finance was hearing other amendments on Medicaid and Medicare, Mr. Roth deemed the patent measure out of order, declaring that it was in the jurisdiction of the Labor Committee and he refused to accept a letter from Labor waiving jurisdiction.

Behind his resolve was Mr. Dole, who had agreed to block a vote at the request of Sen. Jesse Helms, R-N.C., who faces re-election in 1996 and could use the financial help of the U.S. subsidiary of Glaxo, located in North Carolina.

In a perhaps unprecedented move, Mr. Chafee forced a vote on Mr. Roth's decision. Little-used rules required a two-thirds majority to overrule the chair.

Thus a 9-7 vote to overrule failed, despite the majority.

Mr. Roth later declined to comment on whether the ruling had been made under pressure from Mr. Dole. ''I don't discuss my meetings with Sen. Dole,'' he said, ''but this was based on the rules of the Finance Committee.''

[From the Journal of Commerce, Oct. 5, 1995]

THE SENATOR FROM GLAXO?

When Sen. Bill Roth succeeded Bob Packwood as chairman of the Senate Finance Committee, he had a cloud over his head. Sen. Roth, so the thinking went, would be beholden to Sen. Majority Leader Bob Dole and not act independently on committee business. That may have been an unfair rap, but so far it seems to be coming true.

Consider a case involving patents that came before the Finance panel recently. Last fall, as part of the new Uruguay Round trade deal, Congress changed the term for patent protection to make the U.S. standard match the norm in most other countries. An oversight by government lawyers, however, effectively extended the life of a handful of drug patents, denying generic drug companies the right to compete with these patent-holders.

By far the biggest beneficiary of this mistake is British-owned Glaxo Pharmaceuticals, which will earn $3.6 billion by gaining an extra 19 months of patent protection for a single drug—its Zantac anti-ulcer medicine.

To preserve this windfall, Glaxo has enlisted, among others, Sen. Jesse Helms of North Carolina, the state where Glaxo's U.S. subsidiary is located. Facing re-election in 1996, Sen. Helms reportedly went to Sen. Bob Dole and got his support for squelching any attempt to repeal Glaxo's bonus.

When Sens. John Chafee and David Pryor offered an amendment to close the Glaxo loophole, Sen. Roth blocked them. Using a parliamentary ruling from Sen. Dole's office, he ruled the amendment out of order, even though it fell within the committee's purview on health care and trade.

Even though most committee members favored a vote on the proposal, Sen. Roth ignored their pleas. In a move the committee hadn't seen in decades, a majority of members then voted to overrule the chairman on a procedural point, tossing out a tradition of collegiality.

In the end Sen. Roth prevailed, since two-thirds of committee members were needed to overrule him. But he lost this first test of leadership.

TRANSCRIPT FROM NBC NIGHTLY NEWS WITH TOM BROKAW, WEDNESDAY, SEPTEMBER 27, 1995—''IN DEPTH'' SEGMENT

[Brokaw in studio standup.]

BROKAW. More on Medicare reform as Congress looks for ways to save. We've got the shocking story of how some drug companies are cashing in—at your expense.

[Video to footage of Congressional Hearing on Capitol Lawn.]

In the Medicare debate today, House Democrats held their second hearing on the Capitol lawn, protesting what they say is Republican unwillingness to hold official hearings.

[Brokaw in studio standup.]

In the Senate, gridlock as Democrats blocked the Finance Committee from working on the Medicare proposal today. But there is one area where Congress could help save millions of taxpayers dollars—now. NBC's Lisa Myers has this Indepth report.

[Video footage of Florence Davis.]

MYERS. Ninety-year-old Florence Davis takes the prescription drug Capoten for her high blood pressure. A month's supply costs $125 at her pharmacy.

DAVIS. If I could get the generic cheaper, I would.

MYERS. Her son, Norman, pays for the medication.

NORMAN. For all of my mother's drugs, I pay for them. She can't afford it.

MYERS. Mrs. Davis was supposed to be able to buy a cheaper generic version of Capoten beginning last month, cutting the cost by as much as half.

[Video footage of pharmacist dispensing pills in pharmacy.]

But, thanks to Congress, she'll have to wait until at least February, and here's why.

[Cut to video of Myers in Senate Hearing Room showing GATT bill.]

Last year, Congress made a costly mistake in this huge bill implementing the trade agreement called GATT. It gave big drug companies longer patent protection on about a dozen drugs, enabling them to charge high prices without competition.

[Cut to video of Senator David Pryor (Democrat-Arkansas) holding pill bottle.]

PRYOR. They're getting a two billion dollar a year windfall. It is a bonanza. This is an absolute ripoff to consumers and to taxpayers.

[Cut to graphic of ''Big Winners'' showing Bristol-Myers Squibb and Glaxo, with picture of drug products.]

MYERS. The big winners: Bristol-Myers Squibb, maker of Capoten, taken by 15 million Americans last year, and Glaxo, maker of Zantac, an ulcer drug prescribed to 33 million.

[Cut to graphics ''Big Losers.'']

The biggest losers: everyone who uses the drugs.

[Cut to graphic of Zantac.]

Take Zantac, the ulcer drug which costs about $83 a month. Buying generic could cut that cost in half, a big savings if you're on a fixed income.

[Cut to video of Horning.]

HORNING. That can mean the difference between her having lunch or not. It's simply that critical to some of our elderly.

[Cut to video of crowded street scene.]

MYERS. And if you don't use the drugs, you still lose. Taxpayers have to pay $200 million more for these prescriptions under health programs for the poor.

[Cut to video of drug production line.]

It's no wonder drug companies are fighting to save their huge windfall. In fact, they claim it was no mistake at all.

[Cut to video of Mossinghoff.]

MOSSINGHOFF. Congress knew exactly what it was doing. It was extending patents across the board.

[Cut to video of Chafee and Dole talking; video of Chafee.]

MYERS. However, Republican Senator John Chafee says that's not true.

CHAFEE. Each of us that were involved never thought that this was taking place.

[Cut to graphic on campaign contributions.]

MYERS. Still, fixing the problem will be an uphill battle. Glaxo has given $600,000 in campaign contributions in the last two and a half years: $375,000 to Republicans; $236,000 to Democrats.

[Cut to video of senior citizen purchasing prescription.]

Senior groups warn that if Congress does not correct its mistake, it would send a powerful message to voters.

[Cut to video of Horning.]

HORNING. It is a signal that, ''Well, we really don't care about you because, you know, the pharmacies are giving me campaign money.''

[Cut to video of Davis.]

MYERS. Florence and Norman Davis say they can't afford to have Congress and big drug companies conduct business as usual.

Lisa Myers, NBC News, the Capitol.

[From the New York Times, Sept. 28, 1995]

BATTLE OVER BONANZA FOR DRUG COMPANIES

An army of lobbyists has been enlisted to do battle over a loophole in a trade treaty that has created a windfall for the makers of patent drugs.

A Senate committee is considering amending a provision in the General Agreement on Tariffs and Trade that extends the life of patents on prescription drugs. Under the provision, a handful of drug companies would receive billions of dollars in additional profits by having a longer period to sell their products without competition before other companies would be allowed to make low-cost generic alternatives.

On one side are companies like Glaxo-Wellcome, the world's largest pharmaceutical concern, whose ulcer drug Zantac

earns it $2.1 billion a year, a figure that could drop sharply once generic versions of the drug are sold.

On the other side is a coalition of generic drug makers and consumer groups who say that failure to close the loophole will cost consumers billions of dollars.

[From the New York Times, Sept. 28, 1995]

DRUG FIRMS AT ODDS OVER PATENT EXTENSIONS

SPECIAL PLEADERS—A PERIODIC LOOK AT LOBBYING

(By Neil A. Lewis)

WASHINGTON, September 27.—By the time the Senate Finance Committee resumes consideration of the Federal budget's multibillion dollar issues Thursday, some of the nation's largest drug companies will have spent and lobbied heavily against one amendment that hardly amounts to budget dust.

But while its impact on the Federal budget may be minuscule, the measure means a fortune to the drug companies.

The amendment at issue would close what appears to be an unintended loophole in an international trade treaty enacted last year that extends the life of patents on prescription drugs. A handful of drug companies are fighting to protect the provision for billions of dollars in additional profits they would receive by having a longer period to sell their products before other companies could make low-cost generic alternatives. On the other side of the issue are members of the generic drug industry, which in coalition with consumer groups argues that the failure to close the loophole will cost patients billions of dollars.

While both sides have their teams of lobbyists, the major drug companies have enlisted a virtual army of advocates, including one former Senator and several former senior Congressional aides who have been clustering outside the Senate hearing room in which the committee has been meeting this week. One company, Glaxo-Wellcome P.L.C. of North Carolina, which probably has the most at stake, has retained the most influential phalanx of lobbyists.

Donations from Glaxo's political action committee to members of Congress have more than doubled in the most recent reporting period, compared to the same period two years ago, according to records of the Federal Election Commission.

Glaxo, the world's largest pharmaceutical company, has the patent on Zantac, widely used drug to treat ulcers. The drug, which retails for about $2 a tablet, accounts for about $2.1 billion in annual sales for the company, said Nancy Pekarek, Glaxo's manager of corporate relations. This revenue will drop sharply once generic versions of Zantac are permitted.

That the issue of the patent extensions arises from an unintended loophole is generally beyond dispute.

Glaxo's lawyer told Business Week magazine in May that he had ''a Eureka! moment'' when he was poring over the details of the General Agreement on Tariffs and Trade signed into law last year and discovered that the language could be read to extend patents on prescriptions drugs. The drug companies pressed their interpretation on the Food and Drug Administration, which last May reluctantly acknowledged they were correct. Mickey Kantor, the United States Trade Representative who negotiated the treaty has written a letter to the Senate saying the negotiators did not mean to incur this consequence.

Senator David Pryor, an Arkansas Democrat, has been trying to enact an amendment to the budget bill that would do just that, eliminate what he said is a ''windfall'' for the drug companies. His amendment would restore the 17-year limit on a drug company's patent of a new medicine, the period during which other companies are prohibited from making a generic equivalent.

''It's absolutely an unjust enrichment,'' he said. ''A classic case of the law of unintended consequences.''

What happened to create this fortuitous situation for the drug companies was that when the trade agreement was negotiated, it included a provision for bringing all 123 countries onto the same standard for patent protections. It required the United States to switch from granting 17-year patents from the time of their approval to giving 20-year patents from the time of the application for a patent.

Depending on how long it took to gain patent approval, the law gave companies up to three years of extra protection for their products. About 10 drugs are affected, and Glaxo's Zantac would gain 19 extra months of patent protection.

Ms. Pekarek of Glaxo said that her company was not fighting the amendment because of its effect on Zantac, but because of ''a much broader issue of worldwide patient protections.''

She said that it was important not to tamper with the trade treaty because, ''if we do anything to undercut it that would be opening the door for other countries to make special provisions on patents for their products.''

The United States is the world's leader in producing new medicines, and the pharmaceutical industry has long argued that its profits during the patent protection period finance research on new drugs.

Among those Glaxo has employed to lobby the Senate is William Brock, a former Republican Senator from Tennessee. Mr. Brock is also particularly suited to press the point about worldwide patent consistency because he is also a former United States Trade Representative.

He has been making that argument this week in the Republican cloakroom to which he has access as a former Senator. Mr. Kantor, the current trade representative, has disputed that argument.

The amendment sponsored by Mr. Pryor as well as Senator John H. Chafee, a Rhode Island Republican, may come up as early as Thursday.

But its fate is uncertain, since it is a tenet of Capitol Hill that it is more difficult to pass something than to defeat it. Most of the Democrats are expected to support the measure but at least one Senator Carol Moseley-Braun of Illinois declared her opposition today.

Senator Moseley-Braun said through a spokeswoman today that she was a longtime friend of Robert Ingram, president and chief executive of Glaxo. She flew on the company's jet last March to Glaxo's headquarters to give a speech and meet with community leaders.

She said through her spokeswoman, Joanna Slaney, that she opposed the amendment because she believed the trade agreement should not be tampered with.

[From the Food and Drug Inside Report, Sept. 29, 1995]

GLAXO ROLLS OUT ''BIG BUCKS'' CARD IN GATT BATTLE ON CAPITOL HILL

REPUBLICANS UNEASY WITH HEAVY-HITTER LOBBYISTS AND SCORE SHEET ON CAMPAIGN CONTRIBUTIONS BEING TOUTED BY GLAXO

When the congressional staffers working on H.R. 5121 sat down last November to draft the specific language that would implement the GATT in the United States, it must have been very late when the final draft was completed. It would, after all, be understandable that these staffers would be tired after laboring for months on multiple versions of the implementing statute for GATT. The complexities of the GATT Agreement are legion, and even experienced international trade lawyers were hard pressed to provide clear explanations of a great deal of the sections of GATT. The bottom line, borne no doubt from those difficult conditions, the Congress made a mistake.

Like much of the grinding machinery of the legislative process, the impact of that mistake took some time to assess. In this case, the mistake was a simple oversight by the drafters who failed to contemplate the importance of including conforming amendments to the Federal Food and Cosmetic Act and Section 271 of the Patent Act.

Shortly after passage of H.R. 5121, no doubt in the richly paneled offices of one of Washington's expensive law firms, a lawyer by the name of Marc Shapiro was laboring on the language of the newly passed legislation. No doubt it was an effort to advise his client, Glaxo Holding PLC, of what they needed to do to comply with the various. For Marc Shapiro, who is known among his colleagues as a professional with a deep understanding of his craft, it was a mind numbing experience when he read the plain language that set forth Congress' view of how GATT would be implemented in the United States.

In order to comply with an ''international harmonization'' of patent terms with member nations of GATT, the United States adopted changes to the patent term to commence at the date of filing with the patent office and extend for a period of 20 years. That contrasts with the previous U.S. patent law that had provided for a 17-year patent term which commenced from the date of approval of the patent by the Patent and Trademarks Office (PTO).

The GATT includes a section known as Trade-Related Aspects of Intellectual Property Rights (TRIPs) which requires member countries to apply high levels of protections for existing patent holders. The United States fulfilled its obligations under TRIPs by amending the Patent Act of grant owners of patents still in force the benefits of the new terms to the extent that it increased their patent protection term.

But TRIPs also had specific provisions to protect those individuals who had made a ''substantial investment'' in anticipation of the expiration of the patent under the old system. To balance the interests to the existing patent holders, those who had made substantial investment would be required to pay ''equitable remuneration'' to the patent holder.

Marc Shapiro, while sifting through the legislation, had what he characterized to a Business Week reporter as a ''eureka moment'' when he discovered that Congress had extended the patents of a number of Glaxo products, and had provided no protections for generic drug manufacturers even if they had made the required substantial investment.

For generic drug manufacturers, it was a setback. For senior citizens on fixed incomes who rely heavily on access to generic drug products to ease the financial burden of needed prescription drugs, it was a disaster. For low-income families with children who are forced to rely upon generic drugs in difficult economic circumstances where the choice is often not to fill a needed prescription because of cost, it was a horrible calamity. For the U.S. government health care programs like Medicare, Medicaid, Veterans Affairs, Indian Health Service, and the Public Health Service, it is an unmitigated catastrophe.

Glaxo executives and lobbyists, however, were whooping it up like they had just won the Super Bowl. In a certain sense, they had.

The flagship Glaxo product, Zantac, was granted an additional 19 months of patent protection. It was totally unanticipated by Glaxo. Indeed, they had priced their product over the 17-year patent term in anticipation of the old term, and the passage of the new law occurred within months of the expiration of the patent. The overall revenue gain was billions.

Glaxo lobbyists now bristle at the characterization of the revenues raked in during the extended patent term as being ''windfall profits.'' ''That is not fair because we all know that we gave up a lot to the generic industry back in 1984. We're just seeing a justified correction,'' claims one Glaxo lobbyist.

The 1984 Drug Price Competition and Patent Term Restoration Act, commonly referred to as ''Hatch-Waxman,'' did indeed involve a carefully crafted compromise between the brand industry and generic drug manufacturers. The generics got pre-expiration access to patented raw materials to conduct testing to theoretically allow FDA to approve the ANDA on the date of patent expiration. The brand industry got a guarantee of 14 years of market exclusivity despite any delays in FDA review.

Many have credited the Hatch-Waxman Act as having been the catalyst for a rapid expansion of the generic drug industry. Senior citizen groups and consumer advocacy groups have lauded the Act as key to improving the health of financially fragile purchases who often deferred purchasing needed drugs simply because of the high cost of brand name drug products.

There has not been any serious attack on the Hatch-Waxman Act as having been ''unbalanced'' to one side or the other over the first ten years of its existence. But now, in 1995, Glaxo points to the need for restoring some balance to the brand industry for injury heaped on it by Hatch-Waxman.

The Generic Drug Equity Coalition, a group of consumer advocate groups, senior citizen lobbying groups, and generic industry supporters, sees the issue a little differently. ''Glaxo has no legitimate gripe with the proposed fix. It will simply mean they won't get to keep the multi-billion windfall profit they received solely from a legislative mistake. They didn't earn that windfall profit. They don't deserve that windfall profit. But they want to take those profits right out of the pockets of people who can least afford their high prices,'' complained one Coalition FDA Insider.

Capital Hill staffers are caught in a tough situation. Privately, of 33 staffers contacted on this issue, none disagreed with the fact the mistake needed to be corrected. None disagreed that the consumers and government would have to pay unjustified higher prices for products that should have generic competition. All of the staffers agreed that Glaxo did not deserve the billions they would receive from this mistake. But only 1 staffer was absolutely confident Congress would correct the mistake.

''What can we do. Glaxo has made campaign contributions to all of our bosses. The Chairman of the company [Glaxo] has been demanding personal meetings with our bosses. Is there any doubt about the subtle message being conveyed. 'We are here to pick up the chit.' This is going to be a case of pure political conflict, with the consumers on the side of the angels and Glaxo with the gold shillings. I just don't know how it will come out,'' laments one Senate Finance Committee staff FDA Insider.

The battle lines drawn

The political battle lines are not clearly defined. For the generic coalition, Senator John Chafee (R-Rhode Island), Senator Hank Brown (R-Colorado), and Senator David Pryor (D-Arkansas) have been working to correct the mistake in the GATT language. For Glaxo, there is less public enthusiasm, but a lot of fire-power by virtue of the campaign favors that are being called in. Senator Alfonse D'Amato (R-New York) has obviously been pressed into service by virtue of his position as Chairman of the Republican Senatorial Campaign Committee. Some other Republicans are concerned about the appropriateness of the high-level of visibility that D'Amato has taken on the issue, but sources at the Campaign Committee bluntly told FDIR that ''Glaxo was taking no prisoners'' on this issue.

Senator Jesse Helms (R-North Carolina) has dutifully stepped to the plate to help his home state Glaxo workers (the U.S. Glaxo operations are in the Research Triangle in Raleigh, North Carolina). Beyond that, there are only a group of stealth Glaxo supporters who are desperately hoping that something will happen to allow them to get off the end of the Glaxo spear. For most it is a horrible political position to be in to appear to oppose access to lower cost generic drugs for senior citizens and low-income families.

The Congressional Budget Office (CBO) scored the 5-year savings to Medicaid at $150 million. That is no small potatoes to Republicans seeking savings. But that amount is minuscule compared to the $2 billion cost to consumers identified in a Muse & Associates economic impact analysis. At that number the political pain becomes much deeper and the potential for future constituent problems becomes very real.

The strategy for correcting the GATT legislation mistake is to include a provision in the Budget Reconciliation Act as an amendment in the Senate Finance Committee markup. Glaxo supporters are trying to argue the amendment is not germane under the ''Byrd Rule'' since the savings flow to the Medicaid block grants and not to the Federal deficit. But Glaxo critics argue the block grants are unique to the Finance Committee review cycle this time around, and virtually all of the provisions technically trample on the Byrd rule in order to facilitate the block grants being transferred from the Federal Government to the states.

The central substantive argument Glaxo has relied upon has been that any change now would upset the delicate balance with World Trade Organization (WTO) members who have a history of poor enforcement of patent infringements in their countries. Glaxo points to certain language in the GATT and TRIPs they claim was in fact incorporated in the strategy of the H.R. 5121 drafters. The thesis, then, is that there was no error or mistake, but the language was clearly set forth to express the specific intent of the U.S. Congress.

''They must have their fingers crossed behind their backs when they sling that BS up here,'' commented on House Ways and Means Committee staffer. ''It was a mistake, we know it, and they know it.

Senator Chafee wanted to know the truth of the matter, so he sought the advice of USTR Ambassador Micky Kantor. Kantor was succinct in his view: ''This provision [Section 154(c) (1) and (2) of the Patent Act] was intended to apply to all types of patentable subject matter, including pharmaceutical products. Conforming amendments should have been made to the Federal Food Drug and Cosmetic Act and Section 271 of the Patent Act, but were inadvertently overlooked.''

The key part of the Glaxo argument is directed at the problems encountered around the world with poor enforcement of patents, particularly with some members of WTO. They advance the argument that any tinkering with the present language would send a strong message to our trading partners that they need not aggressively enforce patent rights. It is an argument that seemingly was sufficient for Glaxo supporters to hang their hats on.

But Ambassador Kantor punched big holes in that argument, and has left Glaxo very vulnerable to the charge that they are just trying to keep an unjustified windfall profit. It is a message that Glaxo has tried to gussy up with an elite lobbying corps. Former Senator Warren Rudman and former Senator Bill Brock were both brought in to shore up an eroding Glaxo position. That augments a term of virtually every high-powered lobbyist in Washington available to work. ''The 'alligator shoe' crowd is apparently out in force,'' commented one House Commerce Committee staff FDA Insider.

The generic drug industry, on the other hand, seems to have placed its fate in the hands of a rag-tag band of consumer advocates and senior citizen advocacy groups. It seems to be working. Congressional staffers report a substantial interest in the issue among talk show hosts around the country.

''Our phone lines are burning up with senior citizens who are just hopping mad over the prospect we may add costs to drugs. I don't think we want to be in that position,'' observed a Senate staff FDA Insider.

Whatever the Senate Finance Committee does on this issue in the Budget Reconciliation markup, it promises to be a hot issue over the next several weeks. For Marc Shapiro, he is surely hoping his ''eureka moment'' doesn't turn into a ''Maalox minute.'' Certainly it is a comment he wished he could take back and recast it in less flammatory language.

''This battle boils down to a simple issue. Is there any justification for allowing Glaxo to keep the billions of dollars they will get simply from an error in drafting a piece of legislation.

''Did Glaxo earn these windfall profits? No.

''Did Glaxo expect or need these windfall profits to fund R&D for the product? No.

''Did Glaxo project these windfall revenues into pricing to recover a fair return on their investment? No.

''I have not yet heard one compelling argument to justify a vote to let them keep money Glaxo will get on the backs of senior citizens and poor families. Glaxo is getting access to various members because they have been strong campaign contributors. But they didn't buy votes with those contributions, particularly when they have no credible argument to justify themselves. It is only a lot of smoke and mirrors. No substance. It is a no-brainer to me. Vote to protect consumers.''—Senate Finance Committee Staff FDA Insider.

''The Hatch-Waxman Act established a delicate balance in the pharmaceutical industry between the interests of research-based companies and the generic industry. Any responsible look at the proposal by the generic companies would upset that balance and result in a serious injury to the innovator drug industry. We have no reason to apologize for the revenues that result from the research and development efforts of our company. We are responsible in our pricing policies, and we recognize the needs of low-income families in acquiring our products. Truly needy families can get assistance from community organizations we support.''—Glaxo Lobbyist FDA Insider.

''Finally, the extension of the Section 154(c) to pharmaceutical products would not undermine ongoing U.S. efforts to seek high levels of intellectual property protection around the world. We are acting wholly within our rights in establishing the transition

period, as other countries would be if they did the same. Furthermore, we have already established under our law the transition period with respect to all types of patents other than pharmaceutical patents; extending it to pharmaceutical patents would be in no way increase the ability of our trading partners to justify their failure to provide TRIPs-consistent patent protection.''—Ambassador Michael Kantor, the United States Trade Representative, Letter to Senator John H. Chafee, September 25, 1995.

[From the Orlando Sentinel, Sept. 3, 1995]

GATT PUTS GENERIC DRUGS ON HOLD

(By Maya Bell)

MIAMI.—Interested in saving money, Phylis Tannen routinely requests generic prescriptions for her ulcer.

So Tannen, 74, was surprised to learn recently that she would have to wait much longer than expected to buy the less expensive medicine. That's because the patent for Zantac, slated to expire this December, had been extended until July 1997, preventing the release of a generic equivalent until then.

The retired Dade County school principal was even more surprised to learn the convoluted reason for the delay, which could cost her roughly $430 over the life of the extended patent. In implementing the worldwide trade agreement known as GATT, the U.S. Congress inadvertently exempted at least 13 brand-name drugs from generic competition for up to three years.

Among them: Zantac and the high blood-pressure medicine Capoten, among the best-selling drugs in the world.

The oversight may have been unintentional but, outraged consumer groups say, its impact is enormous: Brand-name drug companies, primarily Glaxo Wellcome Inc. and Bristol-Myers Squibb Co., the makers of Zantac and Capoten, will reap nearly a $2 billion windfall at the expense of the public.

Last year, Glaxo sold $2.7 billion worth of Zantac and Bristol-Myers $581 million of Capoten in the United States alone. Together, they accounted for nearly 48 million prescriptions.

Paying most for the delayed availability of the generic drugs, advocates say, will be the elderly, who consume a third of the $64 billion worth of prescriptions sold annually. Because Medicare does not cover the cost of prescriptions, seniors such as Tannen often pay for them out of their own pockets.

''It was an unintended mistake by Congress, but the public will pay dearly for it,'' said Dixie Horning, executive director of the Gray Panthers, a lobbying group for the elderly. ''Not only are the people who can least afford it—senior citizens on fixed incomes—paying more for their drugs than they ought to be, but taxpayers are too. The government, and that means you, is a big buyer of these drugs.''

A study conducted for the Generic Drug Equity Coalition, a consortium of 26 consumer groups and generic-drug companies urging Congress to correct its mistake, estimated the cost of delaying the 13 generic substitutes of $1.9 billion. Sen. David Pryor, D-Ark., the ranking minority member and former chairman of the Senate's Special Committee on Aging, introduced a bill to clarify Congress' intent earlier this month. The bill would not alter the GATT treaty, nor require ratification from other countries.

Florida's U.S. senators, Republican Connie Mack and Democrat Bob Graham, are not involved in the issue yet, but their staffs said they will take a close look at the legislation when they return from summer recess. In the meantime, at least one generic-drug company is taking its fight to enter the market to court.

Should the bill pass, senior citizens and the federal Medicaid program stand to gain some of the biggest savings, said Don Muse, a former analyst for the Congressional Budget Office and author of the coalition study. He projected seniors would save $517 million; the Medicaid program, which covers prescriptions, would save another $205 million, and the Department of Veterans Affairs $21 million. Other big savers would include insurance companies, whose medical plans often require members to elect generic drugs.

The estimated savings are very conservative, the coalition says, because the study assumes the generic products would be only 10 percent cheaper than their brand name equivalents. However, generic drugs have historically debuted at a price about one-fourth less than the brand, quickly falling to 75 percent of the brand cost.

How the General Agreement on Tariffs and Trade wound up hurting consumers such as Tannen while helping companies such as Glaxo is as complicated as the 8,000-page treaty itself. The trouble began when Congress changed U.S. patent law to match the global standard set by GATT. The change extended the life of U.S. patents from 17 years to 20 years, benefiting current patent-holders by up to three years.

But Congress recognized that the change would, as one congressional staffer put it, ''move the goal posts back'' for companies that anticipated a patent expiring and already had a generic product in the pipeline. So Congress devised a mechanism allowing those companies to enter the market on the day the original patent would have expired. The compromise: The generic company would pay the brand-name company a royalty until the extended patent expired.

Everything was fine until the generic-drug companies realized that Congress overlooked the very law that launched their industry in 1984. The law plainly states that a generic drug cannot come to market before the brand's patent expires. Hamstrung by the conflict, the Food and Drug Administration forbade generic-drug companies from selling their products until the extended patents expire.

As a rsult, the prescription drug industry is the only industry in the nation that will benefit from longer patent terms but be exempted from generic competition during the compromise period.

The ruling felt like a kick in the teeth to Patrick McEnany, president of Royce Laboratories Inc., a small but rapidly growing generic drug company in Miami that nearly doubled its sales last year to $6.6 million.

Soon after McEnany joined Royce in 1991, the company set out to develop a generic form for Capoten, which was supposed to lose its patent on Aug. 8. Spending more than $1 million to develop a bio-equivalent, Royce hoped to put the first Capoten substitute on the shelf, a key to capturing the generic market.

''In this business, timing is everything,'' said Robert Band, Royce's chief financial officer. ''Once the shelf space is taken up, it's hard to wrestle it away.''

The FDA ruling, however, extended Capoten's patent for six months, keeping Royce and five other companies from competing with Bristol-Myers until February.

The company counted on attracting an enviable share of the nearly 15 million Capoten prescriptions sold annually during the next six months. Instead it was left with the prospect of having even more generic competitors come February.

Not content to let that happen, Royce picked a fight with Bristol-Myers in U.S. District Court in Miami, winning the first round nine days ago when a judge ruled that the FDA was free to approve Royce's Capoten product.

Bristol-Myers appealed, and the FDA said it would not act on the court action until that appeal was exhausted.

''When we enbarked on this product, we relied on a set of rules and the rules changed—not in the middle of the game, but at the end of the game,'' McEnany said. ''It is an injustice to us and to the consumer.''

Royce is not alone. Novopharm USA Inc., an Illinois-based pharmaceutical company, has millions of dollars worth of its generic form of Capoten sitting in inventory. Worse, Novopharm has a $38-million plant under construction in North Carolina, company president Bill Gunter said. It was where Novopharm planned to begin manufacturing its generic alternative for Zantac this December.

''Now we're scrambling to figure out what we can do to justify that huge, white building,'' Gunter said. ''It's not a simple thing.''

Royce and Novopharm are members of the coalition pushing Congress to correct its oversight. They aren't, however, getting much sympathy from brand-name manufacturers, who argue that it is the generic competitors reaping the windfall. After all, generic manufacturers capitalize on the millions of dollars brand-name companies spend on research and development, coming to market without doing the same science.

Bristol-Myers spokesman Bob Laverty points out that, since Capoten was first approved in 1981 to combat high blood pressure, the company has discovered three other life-saving uses for the drug. In his view, Bristol-Myers has more than earned its patent extension.

''We don't feel this is a windfall because the company has continued to invest in this product over the years,'' Laverty said. ''We've continued to pour research dollars into the product and it has helped consumers tremendously.''

Glaxo paints the GATT flap as a trade issue, not a consumer issue. Company spokeswoman Nancy Pekarek warns that if Congress amends the GATT law to appease the genertic drug industry, it will send a message to other countries that they, too, can tinker with their patent laws to protect a favored industry.

''The law is clear and it should be followed,'' Pekarek said ''Generic companies already have a shortcut and for that shortcut they promised to honor the patent expiration date. Yes, the rules changed, but everybody has to abide by the rules.''

[From USA Today, Aug. 8, 1995]

GATT DELAYED NEW GENERIC DRUGS

(By Anita Manning)

The world trade agreement GATT extended patents on a dozen drugs—including popular blood pressure and ulcer medications—delaying generic manufacturing and costing consumers millions of dollars, consumer advocates say.

The patents were to expire today on Capoten and Capozide and on Zantac in December, but the General Agreement on Tariffs and Trade extends them into 1996 and 1997.

Patents had run 17 years; GATT extended it to 20 years.

''GATT created a windfall for drug companies,'' says Jim Firman of the National Council on the Aging.

In 1994, nearly 15 million prescriptions were written for blood pressure medicine Capoten/Capozide, at $56.29 each wholesale, and more than 33.4 million for the ulcer drug Zantac, at $81.47, says the Generic Drug Equity Coalition.

Steve Berchem, of the trade group Pharmaceutical Research and Manufacturers of

America, says patents are the industry's ''lifeblood.'' ''Patents help companies generate revenue to do further research.''

[From the Los Angeles Times, June 8, 1995]

RULING SHORTENS BRANDED DRUGS' MONOPOLY

Nearly 100 brand-name drugs lost their chance at an extra few years' monopoly in the market Wednesday under a ruling by the U.S. Patent and Trade Office.

At issue is whether the drugs could get two patent extensions, one from a 1984 law and another under a global trade agreement provision that takes effect today.

The General Agreement on Tariffs and Trade extends patent protection to 20 years from the date drug makers file for a patent. Until now, those patents have had a 17-year life from the time they were granted. Current patent holders will get whichever expiration date is later.

A 1984 law has already offered brand-name drugs up to an extra five years' patent life to help offset the time it takes those medicines to get Food and Drug Administration approval for sale.

Makers of brand-name drugs said they were entitled to both extensions, and in March the patent office tentatively agreed. The proposal theoretically could have given some drugs patent protection for a total of 25 years, although the Pharmaceutical Research and Manufacturers Assn. insisted that was highly unlikely.

But the patent office reversed itself Wednesday, ruling that companies that took the 1984 extension can't also get one from GATT. The ruling affects 94 brand-name drugs and means that the longest a medicine will be able to monopolize the market because of the extension is slightly under 22 years.

''American consumers should get a price break on many drugs as a result of the patent office's reversal'' because it opens the market to quicker generic competition, said Sen. David Pryor (D-Ark.).

The brand-name industry was disappointed by the ruling.

''Their March tentative ruling was the correct one from a legal standpoint,'' said Neil Mulcahy, an attorney for the pharmaceutical association.

Another 15 drugs, including the billion-dollar ulcer drug, Zantac, will get the GATT extension.

But Pryor renewed his pledge to fight those drugs' market exclusivity. GATT had included a provision saying cheaper generic versions of these drugs could proceed to the market on the brand name's original expiration date if they paid the competitor compensation. But the FDA last month said prior law invalidated that provision, meaning GATT will postpone generic competition for these 15 drugs.

GENERIC DRUG EQUITY COALITION,
Washington, DC, September 20, 1995.

Hon. WILLIAM ROTH,
Chairman, Committee on Finance, 219 Senate Dirksen Office Building, Washington, DC.

DEAR CHAIRMAN ROTH: As you prepare for action on the reconciliation bill, the Generic Drug Equity Coalition urges you to include language to correct an oversight in the GATT Treaty implementing legislation as it affects the availability of generic drugs.

The Congressional Budget Office has determined that, for budget scoring purposes, Medicaid will save $150 million over five years, if the correction is included in the reconciliation bill.

The GATT treaty extends patents on U.S. products from 17 to 20 years. It also includes transition rules for generic products that were ready to go to market based on the old 17-year patent term. When Congress approved the treaty, however, it failed to change U.S. law to allow the Food and Drug Administration (FDA) to certify generic drugs for marketing during the transition period.

Correcting this oversight will save American consumers almost $2 billion, including $150 million for Medicaid.

Thank you.

Sincerely,

JAMES FIRMAN, Ed.D.

CITIZEN ACTION, CONSUMER FEDERATION OF AMERICA, CONSUMERS UNION,
September 26, 1995.

Hon. WILLIAM V. ROTH, Jr.,
Chairman, Committee on Finance, 219 Senate Dirksen Office Building, Washington, DC.

DEAR SENATOR ROTH: We urge you to include provisions in the budget reconciliation bill that would close the current loophole in FDA law that is delaying American consumers' access to low-cost generic drugs. The Congressional Budget Office (CBO) has estimated that by closing this loophole, you would save the Medicaid system $150 million over the next five years, while consumers would save up to $2 billion.

The General Agreement on Tariffs and Trade (GATT), passed by Congress in 1994, requires the United States to switch from its present system of 17-year patents to 20-year patents. Congress tried to balance the detrimental impact of this provision on competitors by including a clause permitting companies to introduce competing products at the 17-year patent expiration point if the company made significant prior investments and if it paid a royalty to the patent holder. When asked to interpret this clause in the light of the 1984 generic drug law, the FDA found that a loophole exists in the GATT that precludes the agency from certifying generic versions of drugs for marketing until the GATT-extended patents expire.

The extension of patents from 17 to 20 years to currently marketed prescription drugs delays the introduction of low-cost generic drugs into the marketplace. Generic drugs typically enter the market at a much lower cost than the patented brand, and the brand-name drugs which would benefit from this extended patent are among the top-selling drugs used. The result of the FDA's ruling could potentially cost American consumers billions of dollars. The detrimental effects of this patent extension go beyond the individual health care consumer. Taxpayers will be forced to absorb the additional costs for more expensive drugs under the Medicaid program.

The FDA's interpretation of the GATT transition rules does not appear to reflect the intent of Congress when it approved the GATT, nor does it reflect the views of Ambassador Michael Kantor, the U.S. Trade Representative who negotiated the agreement. Mr. Kantor recently wrote to Congress that the transition rule was ''intended by its drafters to be generally applicable and to permit generic pharmaceutical producers to market their products where they had made substantial investments in anticipation of the expiration of the unextended patent terms.'' The unintended effects of the patent extension include diminished market competition, an undeserved windfall to pre-GATT patent holders, and further inflated costs to millions of Americans.

At a time of federal, state and local budget-cutting, health care savings are more important than ever for American consumers. Therefore, we strongly urge you to use the budget reconciliation process to redress this unintended, and potentially costly, effect of the GATT.

Sincerely,

MERN HORAN,
Consumer Federation of America.
GENE KIMMELMAN,
Consumers Union.
CATHY HURWIT,
Citizen Action.

THE NATIONAL COUNCIL ON THE AGING, INC.,
Washington, DC, September 26, 1995.

Hon. ROBERT DOLE,
U.S. Senate, 141 Hart Senate Office Building, Washington, DC.

DEAR SENATOR DOLE: As you prepare for action on the Medicaid reconciliation bill this week, the National Council On the Aging urges you to support language to correct an oversight in the GATT Treaty implementing legislation as it affects the availability of generic drugs. This language will be introduced by Senator Chafee.

The GATT treaty extends patents on U.S. products from 17 to 20 years. It also includes transition rules for generic products that were ready to go to market based on the old 17-year patent term. When Congress approved the treaty, however, it failed to change U.S. law to allow the Food and Drug Administration (FDA) to certify generic drugs for marketing during the transition period.

The Congressional Budget Office has determined that this correction will result in $150 million in Medicaid savings over five years. The correction will save American consumers almost $2 billion.

Lowering the cost of prescription drugs is particularly important for older consumers. Older Americans spend more than any other group on prescriptions. Over one third of the $64 billion spent on prescription drugs come from seniors. This correction will result in over $500 million in savings to older Americans.

We strongly urge you to support the Chafee language in the reconciliation bill allowing consumers faster access to many generic drugs and creating savings for the U.S. budget and for older Americans. Thank you.

Sincerely,

JAMES FIRMAN, ED.D.,
Pesident.

NATIONAL WOMEN'S HEALTH NETWORK,
Washington, DC, September 26, 1995.

Hon. WILLIAM V. ROTH, Jr.,
Chairman, Committee on Finance, Dirksen Senate Office Building, Washington, DC.

DEAR SENATOR ROTH: I am writing on behalf of the National Women's Health Network to urge you to close the generic drug loophole in the GATT during the budget reconciliation process. The NWHN is the only national public interest membership organization devoted solely to women and health.

The availability of low-cost generic drugs saves American consumers billions of dollars every year. Under a recent ruling by the FDA, the patent terms of over a dozen brand name drugs will be extended, costing consumers and taxpayers billions of dollars over the next few years. With the costs of health care continuing to skyrocket while the numbers of uninsured keep going up, consumers cannot afford to pay unnecessarily high prices for medicine. Closing this loophole will save the Medicaid system $150 million over the next five years while it saves consumers close to $2 billion.

Women live longer than men, use more health care services than men, and pay more for drugs out of their pockets than do men. If important generic drugs are delayed, women will suffer most.

The generic drug loophole gives pharmaceutical companies a windfall and hurts American health care consumers. This could not have been what Congress intended when it passed the GATT implementing legislation. Congress should fix the law so that drug companies are not given special treatment while consumers are left holding the bag. I urge you to make this fix in the budget reconciliation bill.

Sincerely,

CYNTHIA PEARSON,
Executive Director.

AMERICAN COLLEGE OF NURSE-MIDWIVES,
Washington, DC, September 25, 1995.

Hon. WILLIAM V. ROTH, Jr.,
Chairman, Committee on Finance, Dirksen Senate Office Building, Washington, DC.

DEAR SENATOR ROTH: The American College of Nurse Midwives urges you to support the Chafee generic drug amendment to the Medicaid reconciliation bill.

If adopted, the Chafee amendment will result in $150 million in Medicaid savings according to the Congressional Budget Office.

The amendment will correct an oversight in the GATT implementing legislation that is delaying the availability of generic substitutes for a dozen popular medications, including the widely prescribed anti-ulcer medication Zantac. United States Trade Representative Mickey Kantor has indicated that this was *not* the intent of the drafters of the GATT implementing legislation.

Left uncorrected, the GATT delay will cost consumers almost $2 billion overall and create an unintended windfall for major pharmaceutical companies.

Please vote to save American taxpayers $150 million by supporting the Chafee amendment.

Thank you.

Sincerely,

KAREN FENNELL,
Senior Policy Analyst.

NATIONAL BLACK WOMEN'S HEALTH PROJECT,
Washington, DC, September 26, 1995.

Hon. WILLIAM V. ROTH, Jr.,
Chairman, Committee on Finance, Dirksen Senate Office Building, Washington, DC.

DEAR CHAIRMAN ROTH: The National Black Women's Health Project (NBWHP), a national self-help and health advocacy organization, would urge you to include a provision in the budget reconciliation bill to close the generic drug loophole in the General Agreement on Tariffs and Trade (GATT). By closing this loophole, you would help to insure that low-income women and their families have access to safe, affordable prescription and over-the-counter medication.

GATT extends patent terms for U.S. products from 17 years to a worldwide term of 20 years. Because many manufacturers had already invested millions of dollars in competing products in anticipation of patent expiration under the original 17-year limit, Congress adopted rules that allow those companies to introduce generic alternatives on the date a 17-year patent would expire, provided they pay reasonable royalties to the patent holder.

Through an error of omission, though, the pharmaceutical industry wasn't included in these transition rules. As a result, makers of lower-cost generic drugs are prohibited from bringing their result to the market until the full 20-year term of patent protection incorporated in the GATT treaty is expired. This loophole will extend the patent terms on more than a dozen drugs—including big-sellers Zantac and Capoten—with a combined $5 billion share of the market.

As an organization dedicated to ensuring the health needs of low-income women, who are disproportionately Black, we believe that access to low-cost generic drugs is crucial. Low-income women and children are more likely to be uninsured and therefore the least likely to afford the high costs of brand name drugs. In addition, low-income families often have limited resources and are forced to delay treatment because of high drug costs. Increasing access to generic drugs will help to improve the quality of health care received by many low-income families.

By closing the generic drug loophole, health care consumers would save approximately $2 billion. Congress would save $150 million in Medicaid costs over the next five years. We urge you to vote in favor of consumers by removing the loophole afforded the pharmaceutical industry in the budget reconciliation bill.

Sincerely,

KIM YOUNGBLOOD.

NATIONAL COMMITTEE TO PRESERVE SOCIAL SECURITY AND MEDICARE,
Washington, DC, September 27, 1995.

Hon. LARRY PRESSLER,
Committee on Finance, U.S. Senate, Russell Senate Office Building, Washington, DC.

DEAR SENATOR PRESSLER: The National Committee to Preserve Social Security and Medicare urges you to support language to correct an oversight in the GATT Treaty implementing legislation that affects the availability of generic drugs. This language will be sponsored by Senators Chafee and Pryor as an amendment to the Medicaid reconciliation legislation this week. The Congressional Budget Office (CBO) has determined that this correction will result in $150 million in Medicaid savings over five years, and some $2 billion in savings to all consumers.

The GATT treaty extends patents on U.S. products from 17 to 20 years. It also includes transition rules for generic products that were ready to go to market based on the old 17-year patent term. When Congress approved the treaty, however, it failed to change U.S. law to allow the Food and Drug Administration (FDA) to certify generic drugs for marketing during the transition period.

In addition to savings for consumers of all ages, lowering the cost of prescription drugs is particularly important for older Americans. Older persons consume about one-third of the $64 billion spent on prescription drugs in the United States.

On behalf of the nearly six million members and supporters of the National Committee to Preserve Social Security and Medicare, we urge you to support the Chafee/Pryor amendment to the reconciliation bill.

Sincerely,

MARTHA A. MCSTEEN,
President.

PUBLIC CITIZEN,
Washington, DC, September 25, 1995.

Hon. WILLIAM V. ROTH, Jr.,
Chairman, Committee on Finance, Dirksen Senate Office Building, Washington, DC.

DEAR SENATOR ROTH: Public Citizen, a national consumer advocacy organization with over 120,000 members, urges you to support efforts to fix the generic drug loophole in the General Agreement on Tariffs and Trade with an amendment to the budget reconciliation bill. This amendment will save the Medicaid system $150 million over the next five years. Consumers will save as much as $2 billion.

For nearly 25 years, Public Citizen and its Health Research Group have been at the forefront of efforts to ensure that safe, effective and affordable drugs are available to American consumers. We were part of the citizens' coalition that supported the Waxman-Hatch Act of 1984 to help consumers save billions of dollars by making more low-cost generic drugs available to the public.

Because of the recently-enacted GATT, which calls for longer durations for monopoly drug patents worldwide, consumers will be forced to pay billions of dollars more instead of less. We urge Congress to restore the law to its original intent so that drug firms do not receive a windfall at the expense of health care consumers.

In this time of massive government budget-cutting and soaring medical costs, health care savings are critically important to the American public. The availability of low-cost generic drugs is one way the marketplace can help bring down the high cost of health care. By extending the duration of monopoly patents on more than a dozen drugs, the GATT will add billions of dollars to consumers' medical costs at a time when they can least afford it.

We urge you to support efforts to protect consumers' health and taxpayers' pocketbooks by fixing the generic drug loophole in the budget reconciliation bill.

Sincerely,

MICHAEL CALABRESE,
Executive Director,
Congress Watch.

U.S. PUBLIC INTEREST RESEARCH GROUP, NATIONAL ASSOCIATION OF STATE PIRGS,
Washington, DC, September 25, 1995.

Hon. WILLIAM V. ROTH, Jr.,
Chairman, Committee on Finance, Dirksen Senate Office Building, Washington, DC.

DEAR SENATOR ROTH: I am writing on behalf of the U.S. Public Interest Research Group to urge you to fix the generic drug loophole in the General Agreement on Tariffs and Trade as part of the budget reconciliation bill. U.S. PIRG is the national lobbying office for state Public Interest Research Groups. PIRGs are non-profit, nonpartisan consumer and environmental advocacy groups with members around the country.

Because of a loophole in the GATT that is being eagerly exploited by profiteering drug companies, American consumers face unnecessary higher costs for prescription drugs at the same time as overall health care costs are skyrocketing. Hundreds of millions of taxpayer dollars and billions of consumer dollars are at stake in this critical fight; the health of millions of Americans absolutely depends on affordable access to low-cost generic drugs.

I urge you to restore the original intent of the GATT's implementing language by closing the generic drug loophole in the budget reconciliation bill. Now is the time to stop rapacious drug companies from misusing GATT to gouge the sick and elderly.

Sincerely,

EDMUND MIERZWINSKI,
Consumer Program Director, U.S. PIRG.

UNITED SENIORS HEALTH COOPERATIVE,
Washington, DC, September 26, 1995.

Hon. WILLIAM ROTH,
Chairman, Committee on Finance, Senate Dirksen Office Building, Washington, DC.

DEAR CHAIRMAN ROTH: The United Seniors Health Cooperative urges you to support language to correct an oversight in the GATT Treaty implementing legislation as it affects the availability of generic drugs. This language will be introduced by Senator Chafee as part of action on the Medicaid reconciliation bill this week. The Congressional Budget Office has determined that this correction will result in $150 million in Medicaid savings over five years.

The GATT treaty extends patents on U.S. products from 17 to 20 years. It also includes

transition rules for generic products that were ready to go to market based on the old 17-year patent term. When Congress approved the treaty, however, it failed to change U.S. law to allow the Food and Drug Administration (FDA) to certify generic drugs for marketing during the transition period.

Lowering the cost of prescription drugs is particularly important for older consumers. Older Americans spend more than any other group on prescriptions. Over one third of the $64 billion spent on prescription drugs come from seniors. This correction will result in $2 billion in savings to all consumers and over $500 million in savings to older Americans.

We strongly urge you to support the Chafee language in the reconciliation bill allowing consumers faster access to many generic drugs and creating savings for the U.S. budget and for older Americans. Thank you.

Sincerely,

ESTHER PETERSON,
Vice Chair.
EDMUND H. WORTHY, JR.,
President and CEO.

UNITED HOMEOWNERS ASSOCIATION,
Washington, DC, October 18, 1995.

Senator DAVID PRYOR,
U.S. Senate, Senate Office Building, Washington, DC.

DEAR SENATOR PRYOR: During Senate consideration of the reconciliation bill, Senators Chafee and Pryor will offer an amendment which will save Medicaid $150 million and consumers about $2 billion. The savings can be realized if a prior oversight by Congress is corrected. The oversight by Congress occurred when the General Agreement on Tariffs and Trade (GATT) implementing legislation was adopted,

GATT extends U.S. patents from 17 to 20 years. It also includes ''grandfather'' rules for generic products, including drugs, that were ready to go to market based on pre-GATT patent expiration dates. Congress, however, failed to change the law to allow the Food and Drug Administration to apply to grandfather rules to generic drugs.

As a result, consumers will spend almost $2 billion more for a dozen popular medications, such as Capoten and Zantac, for which 63 million prescriptions were written in 1994.

Senators Chafee and Pryor will offer an amendment to the reconciliation bill to close the GATT loophole.

Congress can save consumers almost $2 billion, including $150 million in Medicaid savings (according to the CBO), by allowing the FDA to apply the grandfather rules to generic drugs.

Such a change would, according to U.S. Trade Representative Mickey Kantor, be wholly consistent with the intent of the drafters of the GATT Treaty.

The United Homeowners Association urges you to support the Chafee/Pryor amendment to the reconciliation bill.

Thank you.

Sincerely,

JORDAN CLARK,
President.

NATIONAL COALITION FOR HOMELESS VETERANS,
Washington, DC, September 27, 1995.

Hon. WILLIAM ROTH,
Senate Finance Committee, Senate Dirksen Office Building, Washington, DC.

DEAR SENATOR ROTH: On behalf of the more than 200 community-based non-profit programs around the country who provide services for homeless veterans, I am writing to urge you to support the Chafee generic drug amendment to the Medicaid reconciliation bill. The amendment will correct an oversight in the GATT treaty implementing legislation thereby saving consumers $2 billion, including $21 million in direct savings for the Department of Veterans Affairs which could be better used to provide support for local programs who assist needy veterans—instead of being spent on high cost pharmaceuticals.

The Food and Drug Administration has determined that it cannot certify generic versions of popular drugs such as Capoten and Zantac for marketing until the GATT-extended patents expire, thereby delaying the availability of lower priced generics. We do not believe that this is what Congress intended when it approved the GATT treaty in 1994. Specific transition rules were included in GATT implementing legislation to allow generic products to be marketed based on pre-GATT patent expiration dates. Congress, however, inadvertently failed to include conforming amendments to the Federal Food, Drug and Cosmetics Act to allow the FDA to certify the generic drugs for marketing.

It is essential to bring generic drugs to the marketplace as soon as possible to meet the medical needs of veterans and to help the Veterans Health Administration save money. Secretary of Veterans Affairs Jesse Brown estimates that failure to pass this amendment could cost the VA's health budget a significant amount of money. In these times of continuing budget cuts, it is vital that the VA be able to target its limited resources where the need is the greatest.

We urge you to support the Chaffee amendment which will allow the FDA to use pre-GATT patent expiration dates to determine when generic drugs can be certified for marketing and made available to the Department of Veterans Affairs in a manner consistent with the GATT transition rules.

Sincerely,

RICHARD FITZPATRICK,
Executive Director.

PARAQUAD INC.,
St. Louis, MO, September 22, 1995.

Memo to: Members of the Senate Finance Committee.
Re: Medicaid Bill.

I write on behalf of members of the Paraquad community—many of whom are users of prescription medication—to urge you to support the Chafee amendment.

Senator Chafee is proposing a change to U.S. drug legislation that would accelerate the development of generic drugs that now are kept off the market by the GATT agreement.

We believe Congress never intended for the GATT to block generic drugs from being made available quickly to American consumers.

Accordingly, the Chafee amendment merely restores the original intent of Congress.

For example, a generic substitute for the popular anti-ulcer drug ''Zantac'' won't be available to American consumers until July 1997—despite the fact that it originally was to be available in December of this year.

Senator Chafee is asking the Finance Committee to make the necessary change as part of the pending Medicaid savings bill. That is because the American taxpayer will have to pay an additional $150 million for Zantac and other drugs for Medicaid recipients that would be required if the generic substitutes were available.

Many members of the Paraquad community are persons of limited income. Many depend on Medicaid. With cost pressures rising, we join with responsible elected officials like Senator Chafee in urging that where cost savings may be realized at no less of quality, the should be.

Please vote ''Yea'' for the Chafee amendment.

Thank you.

Sincerely,

MAX STARKLOFF,
President, Paraquad Inc.

CONSUMER PROJECT ON TECHNOLOGY,
Washington, DC, September 27, 1995.

Hon. WILLIAM ROTH,
Finance Committee, U.S. Senate, Washington, DC.

DEAR SENATOR ROTH: I am writing to express the Consumer Project on Technology's support for the Chafee generic drug amendment to the Medicaid reconciliation bill. This amendment seeks to correct an error by the previous Congress, which extended the patent terms for several widely used drugs. As you know, investment incentives are forward looking, and actions which award post hoc monopolies on pharmaceutical drugs which are already on the market are economically inefficient. This retroactive extension of monopoly marketing rights is costing American consumers billions of dollars, and should be immediately corrected.

The U.S. Congress and the Clinton Administration have already given the pharmaceutical industry extremely favorable treatment in a wide range of areas, such as the complete lack of price controls on drugs, favorable tax treatment, billions of dollars in direct research subsidies from the National Institutes of Health (NIH) and other federal agencies, and the recent decision by NIH to abandon the reasonable pricing clause for drugs invented by government scientists. We hope that on this issue Congress will demonstrate concern for the problems faced by consumers in obtaining health care.

Sincerely,

JAMES P. LOVE,
Director, Consumer Project on Technology.

Mr. PRYOR. Mr. President, I yield the floor.

Mr. DORGAN addressed the Chair.

The PRESIDING OFFICER. The Senator from North Dakota.

Mr. DORGAN. Mr. President, my understanding is that we are proceeding under a 1-hour morning business allotment?

The PRESIDING OFFICER. We are in morning business.

Mr. DORGAN. Is there an hour reserved under my name or the minority leader?

The PRESIDING OFFICER. There is time under the minority leader, 1 hour.

Mr. DORGAN. Mr. President, with the consent of the minority leader, let me yield myself as much time as I may consume under that 1 hour.

The PRESIDING OFFICER. Without objection, it is so ordered.

THE RECONCILIATION PROCESS

Mr. DORGAN. Mr. President, I was interested in the comments by the Senator from Arkansas. He is correct about this and so many other things. It is interesting to me that there are so many special deals going on these days for special interests, especially in the reconciliation bill and, also, in some of these recent appropriations bills.

It makes me think of going into a shopping center. There you see the sign that says, ''Food Court.'' You look around at the food court, and the entire thing is full of all these little places where you get food. Well, we